CONFIDENTIAL

MAY 1 4 2003

Camino® Single Parameter Monitor

Model SPM -1

510(k) SUMMARY

Submitter's name and address:

Integra NeuroSciences
5955 Pacific Center Blvd.
San Diego, CA 92121, USA

Contact person and telephone number:

Nancy A. Mathewson, Esq.
Director, Regulatory Affairs
(858) 622-2737

Date summary was prepared:

March 24, 2003

Name of the device:

Proprietary Name:	
a. Modified:	Camino® Single Parameter Monitor, Model SPM - 1
b. Unmodified:	Camino® Multi-Parameter Monitor Model MPM-1, cleared 12/20/96 under 510(k) K962928
Common Name:	Intracranial Pressure Monitor
Classification Name:	Intracranial Pressure Monitoring Device Product Code GWM, 21 CFR 882.1620
Classification Panel:	Neurology Device Panel

Substantial Equivalence:

The predicate device is the Camino® Multi-Parameter Pressure Monitor, cleared to market under 510(k) K962928.

Device Description:

The SPM-1 is an intracranial pressure monitor which features continuous mean Intracranial Pressure (ICP) display, high ICP alarm, and bedside monitor capabilities. The SPM-1 is a modified MPM-1 ICP monitor. It contains the same circuit boards as the

MPM-1 but with fewer components, based on the scaled down features (no waveform display, temperature monitoring or ability to calculate CPP).

The SPM-1 is supplied with a PAC-2 Pre-Amp Cable, and a PMIO-SPM Patient Monitor Cable. Non-sterile adapter cables (REF ICP-XX) are used to interface the PMIO-SPM cable to specific bedside monitors. These non-sterile cables come in many configurations, which facilitate data transfer between the PMIO-SPM cable and a specific brand of external bedside monitor.

The following Camino® 110-4 Series ICP catheters are intended to be used with the SPM-1: 110-4B (Ventricular Bolt Pressure Monitoring Kit), 110-4G (Post Craniotomy Subdural Pressure Monitoring Kit), 110-4HM (Micro Ventricular Bolt Pressure Monitoring Kit), and 110-4L (Intracranial Pressure Monitoring Catheter with Licox® IMC Bolt Fitting). The use of temperature catheters is not recommended with the SPM-1.

Statement of Intended Use:

The MPM-1 and SPM-1 are both intended to be used by a qualified NeuroSurgeon when the measurement of intracranial pressure (ICP) is considered clinically important.

Safety:

The SPM-1 underwent numerous safety tests, including testing to IEC 60601-1 and UL 2601.In addition, the SPM-1 was subjected to extensive performance testing. Results of the testing showed that the monitor design was technically sound and the product safe for its intended use.

The SPM-1 manufacturing process complies with the United States Food and Drug Administration and European Standards for the manufacturing of medical devices.

Conclusion:

In summary, the Camino® SPM-1 Intracranial Pressure Monitor described in this submission is substantially equivalent to the unmodified predicate device and the modifications made do not affect the intended use or fundamental scientific technology of the device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 14 2003

Ms. Nancy A. Mathewson, Esq.
Director, Regulatory Affairs
Integra NeuroSciences
5955 Pacific Center Boulevard
San Diego, California 92121

Re: K031086
Trade/Device Name: Camino® SPM-1 Intracranial Pressure Monitor
Regulation Number: 21 CFR 882.1620
Regulation Name: Intracranial pressure monitoring device
Regulatory Class: II
Product Code: GWM
Dated: March 24, 2003
Received: May 1, 2003

Dear Ms. Mathewson:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97) you may obtain. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Miriam C. Provost

for Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

APPENDIX B

Indications for Use Statement

510(k) Number K031086

Device Name: Camino® SPM-1 Intracranial Pressure Monitor

Indications The Camino® SPM-1 Intracranial Pressure Monitor is indicated for use when direct measurement of intracranial pressure (ICP) is clinically important.

Miriam C. Provost
(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K031086

PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use_____
(Per 21 CFR 801. 109)